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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/364,343	07/30/1999		JACQUELINE R. DOYLE	KJ-100	9327
7	590	01/18/2005		EXAM	INER
Arthur A Smith Jr c/o Kenneth Short				MENDEZ, MANÜEL A	
52 Manatee Ro			ART UNIT	PAPER NUMBER	
Weymouth, M	A 02189		3763		

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/364,343

Filing Date: July 30, 1999 Appellant(s): DOYLE ET AL.

Arthur J. Smith, Jr., Esq. For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed March 5, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 1 to 8.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement indicating that claims 1-8 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

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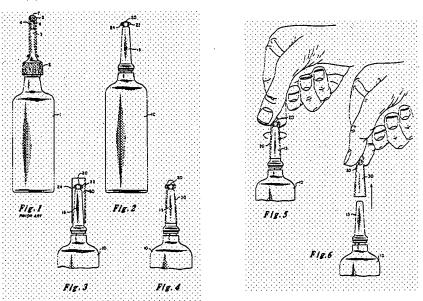
(9) Prior Art of Record

4,752,288	Hussey	06-1988
4,894,053	Reddick	1-1990
2,135,052	Rose	11-1938
6,066,325	Wallace, et al.	05-2000

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

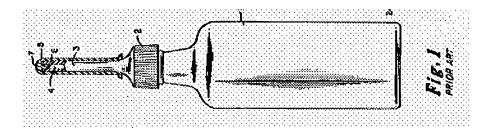
Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by **Hussey**. This rejection is set forth in the Final Office Action, mailed on December 1, 2001, resent to applicant on February 7, 2002, and resent again on August 1, 2002.



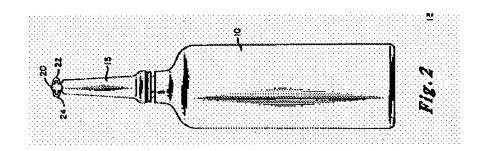
The cited patent shows in figures 1-6 (above), a flexible chamber (1,10) having an internal volume containing enema fluid (which is considered a sterile solution), the chamber having an orifice, a nozzle (15) having a first opening at one end and a second opening at the other end, wherein the first opening is affixed to the orifice of the

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chamber and the second opening dispenses the enema fluid, a protective tip (20) affixed to the second opening of the nozzle maintaining the solution in a sterile state, and a removable packaging band (30) around the protective tip.

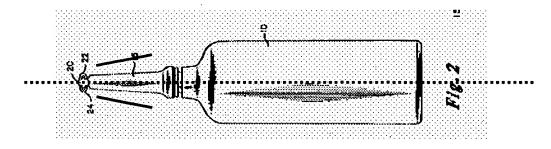


In relation to **claim 3**, figure 1 (above) shows a screw-on cap (2) to affix the first opening to the orifice of the chamber. Importantly, in column 2, lines 3-4, the specification states, "Screw cap 2 has an elongated rectal tip 3 which is coated with a suitable lubricant".



In relation to **claim 4**, figure 2 (above) shows a one-piece enema unit.

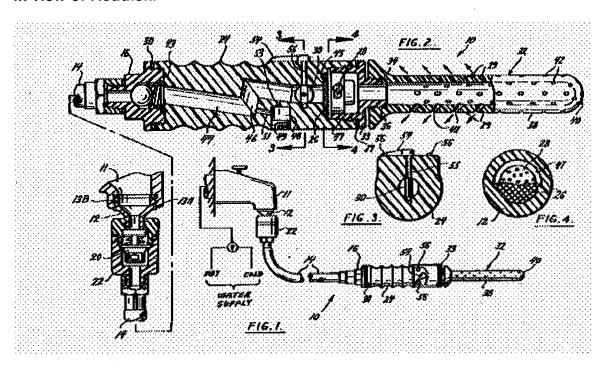
Furthermore, referring to figure 2, in column 3, lines 3-5, the specification states, "Rectal tip 15 and portion 10 may be **molded** in one piece".



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In relation to **claim 5**, figure 2 (above) shows an angled nozzle (15). Please note that the external surface of nozzle (15) is tapered, and therefore, can be considered an angled nozzle. It is noted for the record, that in the final office action, the examiner confused claim 5 for claim 6 and vice versa. However, the rejections for both of these claims can be maintained as they stand.

Claim 2 is rejected under 35 U.S.C. 103 (a) as being unpatentable over **Hussey** in view of Reddick.

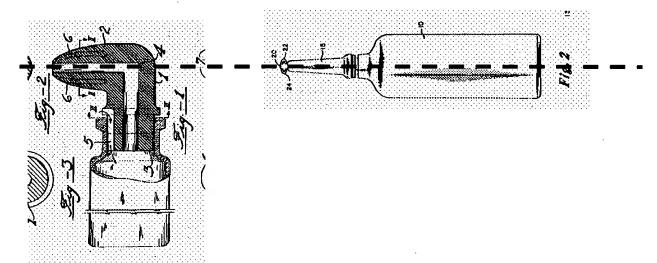


The Hussey Patent does not disclose the use of a filter located at the first opening of the nozzle. However, the use of filters in nozzles is conventional in the art as evidenced by the teachings of Reddick. In figure 2 of the Reddick Patent (above), items (45) and (28) are filters located in the first opening of the nozzle. Accordingly, for a person of ordinary skill in the art, it would have been obvious to modify Hussey by

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enhancing nozzle (15) with a filter as taught by Reddick since Reddick suggests in column 5, lines 63-67, that the filters can be used to remove particulate matter and bacteria from the sterile solution, eliminating the possibility of infections.

Claim 6 is rejected under 35 U.S.C. 103 (a) as being unpatentable over **Hussey** in view of Rose.



Again, it is noted for the record, that in the final office action, the examiner confused claim 5 for claim 6 and vice versa. However, the rejections for both of these claims can be maintained. Please note that both, Hussey and Rose disclose dispensers wherein the nozzle is straight. Accordingly, for a person of ordinary skill in the art, modifying a nozzle with an angled or a straight shape would have been considered obvious in view of the conventionality of both, angled and straight nozzle designs.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussey in view of Wallace, et al. Hussey does not disclose a dispenser having a sterile solution containing sodium chloride and/or distilled water. The examiner would like to point out that all the references utilized in this rejection are capable of infusing

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substances containing the disclosed percentages of sodium chloride and/or distilled water. Therefore, since the dispenser of Hussey is capable of infusing said specific concentrations, the subject matter of claims 7 and 8 is considered to be inherent. Importantly, Wallace, et al., demonstrates in column 16, lines 14-24, that it is conventional to use dispensers with nozzles to infuse substances with various concentrations of sodium chloride and distilled water. Based on the teachings of Wallace, et al., a person of ordinary skill in the art would have considered an obvious design alternative the use of the dispenser of Hussey in combination with any fluid concentration. The fact that the applicant elected to claim "0.9 percent USP sodium chloride" and/or "0.9 percent distilled water" does not per se makes the claims patentable since it is well known in the art that a dispenser can be utilized to infuse any substance and concentration thereof.

(11) Response to Argument

Applicant's arguments have been fully considered, but are deemed not persuasive. In relation to the term "one-piece", the court in <u>In re Larson</u>, 340 F.2d 965, 144 USPQ 347, 349 (CCPA 1965), stated that the difference between a one-piece or multiple piece design is an obvious design choice. Therefore, the term "one piece" does not add any patentable weight to the claim.

Additionally, the phrases "non-invasive" and "which is disposable in any container" are considered intended uses of the dispenser. The court in <u>In re Casey</u>, 152 USPQ 235 (CCPA 1967), stated that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the

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prior art in order to patentably distinguish the claimed invention from the prior art. The phrases cited above do not result in any structural difference, and therefore, do not overcome the rejections of record.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Manuel Mendez Primary Examiner Art Unit 3763

December 16, 2004

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